



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/729,415

12/05/2003

Paul Kudrna

PA047A

8381

57346 7590 10/29/2007
HEATHER AKARTSOUNES
520 W. ERIE STREET
SUITE 210
CHICAGO, IL 60610

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

10/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,415	KUDRNA ET AL.	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-28 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-19, 24 is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-14, 20-23, 25-28, 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413):
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 July 2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-3, 5, 26-28, 30, 33, and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kheiri**, US Patent No. **6,364,889** in view of **Briggs**, U.S. Pub. No. **2004/0049219**.

Claims 1-3, 26, 30: Kheiri discloses an electronic lancing device that uses magnetic forces. **Figure 2** is a good representation of the device.

Kheiri discloses a magnet **50**, a bobbin **35** ("member") capable of being affected by magnetic forces emanating from the magnetic element and a lancet **30** (col. 4, lines

Art Unit: 3734

19-20) movable between a withdrawn position and a piercing position and adapted to be movable from the withdrawn position to the piercing position by movement of one of either the permanent magnetic element or the member, or bobbin, which is movable from a "retracted" ("withdrawn") position to an "activated" ("piercing") position along with a removably attached lancet **30** relative to the other of either the magnetic element of the member (col. 4, lines 44-55). Kheiri discloses a bobbin **35** with a second tubular body member **515** that is wrapped by a coil of wire **520** (col.5, lines 50-51), which is controlled by an electronic circuit (col 1, lines 60-62). The electric circuit **40** is able to direct current through parts of the coil of wire **520** on bobbin **35**, such that the bobbin **35** is capable of being both attracted to or repulsed by the magnet **50** (col. 7, lines 14-18 and 39-42). The electric current **40** can be considered the "arming element" in that it moves the lancet from the piercing position to a retracted, or "armed" position, so that it is ready for piercing.

Kheiri does not expressly disclose using a permanent magnet that does not use an external energy source.

Briggs teaches a lancet device that uses magnets. **Figure 20** is a good representation of the device.

Briggs teaches using a permanent magnet that does not use an external energy source – that a coil that is activated by electromagnetic energy can be replaced by a permanent magnet (page 11, paragraph 172). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a permanent magnet rather than an electromagnet, as taught by Briggs, in order for the lancet to have a zero point

or rest position without the consumption of electrical energy from a power supply (page 11, paragraph 173).

Claim 5: Kheiri discloses a firing button **22** ("activator") that is connected to at least one wire leading to the electronic circuit **40** that controls the movement of the bobbin **35**, and therefore the lancet **30**, from a retracted position to a piercing position (col. 4, lines 57-59).

Claims 27-28 and 33-34: Kheiri discloses a magnet **50** that has a generally cylindrical body member **405** (see col. 5, line 33). Also, bobbin **35** has a generally tubular body member **511** (see col. 5, lines 66-67). The bobbin **35** is disposed over the magnet **50** (see col. 1, lines 59-60), which would suggest that the inner diameter of the bobbin is capable of accommodating the diameter of the magnet so as to permit the bobbin to be disposed over the magnet. Kheiri discloses a steel block **52** that is coaxially centered and mounted on top of the cylindrical magnet **50**, and the steel block **52** affecting a member 360 degrees by either attracting and pulling the member towards the magnetic element and brings the majority of the magnetic flux lines to intersect the coils disposed around the bobbin **35** (col. 6, lines 43-46).

Kheiri does not expressly disclose using a permanent magnet that does not use an external energy source.

Briggs teaches using a permanent magnet that does not use an external energy source – that a coil that is activated by electromagnetic energy can be replaced by a permanent magnet (page 11, paragraph 172). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a permanent magnet rather

Art Unit: 3734

than an electromagnet, as taught by Briggs, in order for the lancet to have a zero point or rest position without the consumption of electrical energy from a power supply (page 11, paragraph 173).

4. **Claims 4, 6-11, 13-14, 16-17, 20-23, and 31-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kheiri and Briggs**, and further in view of **LeVaughn**, US Patent No. **6197040**.

Claim 4: Kheiri and Briggs disclose all claimed structures of the lancet device (see explanations for Claims 1,2-3,5, paragraph 3), except for the lever member.

LeVaughn teaches a lancing device with a releasable connector **28** ("lever"), or cantilever latch, which has a cantilever arm for releasable contact with lancet holder **20**, and has teeth **50** that engage with teeth **52** on the holder (Figures 2 and 7-7A, col. 4, lines 42-44). This is achieved by a slider **26** that pushes the lancet holder **20** in a cocked position, as well as a forward position, as it pushes down on the releasable connector **28** forcing the engagements between the teeth **50** and **52** together, preventing movement (col. 4, lines 15-20). The releasable connector **28** prevents the lancet holder **20** and slider **26** from moving unintentionally; and allows for the cocking and ejecting mechanisms not to be directly linked (col. 2, lines 8-10, 24-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a lever member, as taught by LeVaughn, to Kheiri and Briggs for holding the bobbin **35** in order to mechanically separate the retracted and piercing positions to avoid unintentional piercing of the lancet.

Art Unit: 3734

Claims 6 and 31: Kheiri and Briggs disclose all claimed structures of the lancet device (see explanations for Claims 1-3,5), except for the lever member, which is explained above in Claim 4.

Note: Kheiri discloses all claimed structures for Claims 7, 12-14, 20, 23, and 29 which are all dependent on Claim 6, but are rejected under 35 U.S.C. 103(a) based on the lack of the lever member in Claim 6 (see explanation for Claim 4), and therefore provide disclosures for only the additional claimed structures as anticipated by Kheiri.

Claims 7 and 13: Kheiri discloses a bobbin **35** with a second tubular body member **515** that is wrapped by a coil of wire **520** (col.5, lines 50-51), which is controlled by an electronic circuit (col 1, lines 60-62). The electric circuit **40** is able to direct current through parts of the coil of wire **520** on bobbin **35**, such that the bobbin **35** is capable of being both attracted to or repulsed by the magnet **50** (col. 7, lines 14-18 and 39-42). The electric current **40** can be considered the "arming element" in that it moves the lancet from the piercing position to a retracted, or "armed" position, so that it is ready for piercing. Kheiri discloses a magnet **50** that has a generally cylindrical body member **405** (see col. 5, line 33). Also, bobbin **35** has a generally tubular body member **511** (see col.5, lines 66-67). The bobbin **35** is disposed over the magnet **50** (see col. 1, lines 59-60), which would suggest that the inner diameter of the bobbin is capable of accommodating the diameter of the magnet so as to permit the bobbin to be disposed over the magnet.

Kheiri does not expressly disclose using a permanent magnet that does not use an external energy source.

Briggs teaches using a permanent magnet that does not use an external energy source – that a coil that is activated by electromagnetic energy can be replaced by a permanent magnet (page 11, paragraph 172). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a permanent magnet rather than an electromagnet, as taught by Briggs, in order for the lancet to have a zero point or rest position without the consumption of electrical energy from a power supply (page 11, paragraph 173).

Claim 8: Kheiri discloses a housing **10** that provides an encasing for the lancing device **5**, which includes the lancet **30**, magnet **50** and bobbin **35**, the mechanical or electrical force, the lever member, and the activator (col. 4, lines 21-25).

Kheiri does not expressly disclose using a permanent magnet that does not use an external energy source.

Briggs teaches using a permanent magnet that does not use an external energy source – that a coil that is activated by electromagnetic energy can be replaced by a permanent magnet (page 11, paragraph 172). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a permanent magnet rather than an electromagnet, as taught by Briggs, in order for the lancet to have a zero point or rest position without the consumption of electrical energy from a power supply (page 11, paragraph 173).

Claim 9-11: The lancet **30** is in the retracted position when it is fully within the end cap **25**, and in the activated position when it has advanced from the end cap **25** – the end cap **25** can be considered part of the “housing” here. Kheiri discloses a removable end

cap **25**, which allows for removal and insertion of a lancet **30** in preparation for use (col. 3, line 67 and col. 4, lines 1, 13-14). The end cap **25** also allows control for the depth of puncture, or is an "adjuster" (col. 3, line 58).

Claim 14: Kheiri discloses a lancet **30** that is removably attached to a bobbin, or "member," and therefore is in communication with the collar such that movement of the collar results in corresponding movement of the lancet (col.3, lines 52-53).

Claim 20: The lancet **30** is in the retracted position when it is fully within the end cap **25** selectively connected to or removed from the housing, and in the activated position when it has advanced from the end cap **25** – the end cap **25** can be considered part of the "housing" here. Kheiri discloses a removable end cap **25**, which allows for removal and insertion of a lancet **30** in preparation for use (col. 3, line 67 and col. 4, lines 1, 13-14). The end cap **25** also allows control for the depth of puncture, or is an "adjuster" (col. 3, line 58).

Claims 21-22 and 32: See explanation for Claim 4. The releasable connector **28** ("lever"), or cantilever latch, is similar to the button switch **150** disclosed by the applicant, in that its teeth **50** engages with the teeth **52** on the lancet holder **20** in order to prevent movement in the armed position. It is also similar to the activator means in that is capable of releasing the engagement between the teeth. The teeth **52** on the lancet holder **20** of LeVaughn are in a planar orientation, however it would be obvious to one skilled in the art at the time of invention to modify the teeth of in a circumferential manner on the bobbin **35** of Kheiri when combining the releasable connector **28** with the

lancet device of Kheiri in order to properly hold the cylindrical bobbin **35** in the armed position.

Claim 23: The electric current **40** can be considered the "arming element" that mechanically moves the bobbin **35** in that it moves the lancet from a withdrawn position to an "armed" position, so that it is ready for piercing (col. 4, lines 57-59).

22. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kheiri, Briggs, and LeVaughn**, as applied to Claim 6 above, and in further view of **Simons et al.**, US Patent No. **5871494**.

Claim 25: Kheiri and Briggs disclose all claimed structure of the lancet device (see explanations for Claims 1,2-3,5), except for the dial adjuster and follower for controlling the piercing position. Simons et al. teaches a depth adjuster **560** ("dial adjuster") that is threaded with a cocking tube **562** ("follower") (col.11, lines 64-66), and is rotated causing the cocking tube **562** to move to a position that determines the location of flange **572**, or a limiting stop, which in turn determines how far the lancet **216** can extend forward (col.12, lines 65-75 and col.13, lines 1-9). This design allows a user to control the depth of penetration for optimal blood sampling and pain level (col.13, lines 15-17). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a depth adjuster and cocking tube, as taught by Simons et al., to the device of Kheiri and Briggs, as well as the lever member of LeVaughn, in order to benefit from user control for improving blood sampling and lowering pain level.

Allowable Subject Matter

23. Claims 15-19, and 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 15-17: The collar, or "member," is interpreted as traveling towards the magnetic element after the activator releases the member, meaning that the member is away from the magnetic element in the armed, or withdrawn, position and therefore is *separate* from the steady-state position wherein the magnetic element holds the member within it or is disposed around it.

Claims 18-19: The outer shaft moving relative to the inner shaft is interpreted as the inner shaft not moving, but the other shaft does move. Also, the lancet is capable of being connected to and removed from the outer shaft.

Claim 24: The internal spring is interpreted as a connection between the arming member and the housing.

Response to Arguments

Applicant's arguments filed 25 September 2006 have been fully considered but they are not persuasive.

Applicant generally argues that the device of Kheiri is not a "permanent" magnetic member, but uses an electric current, and that a simple magnet is not the same as an electromagnetic field. The examiner disagrees, and maintains the rejections above. "Permanent" may be interpreted as the position (as it is "stationary

Art Unit: 3734

magnet" in Kheiri), and is not necessarily communicative of a "simple magnet," since a "permanent magnetic element" is not clearly distinguishable over an electromagnet, and it is not defined in the specification. Therefore, the device of Kheiri reads on the limitation of "permanent magnetic element."

Applicant generally argues that end cap **25** of Kheiri is not part of the housing **10**, although it is clear in Figure 1 that the end cap serves as an extension of the housing in that it clearly houses the lancet **30**. In any event, the examiner disagrees and maintains the rejection of Claim 8 (see paragraph 19) using the housing of Kheiri, which reads on the limitation of "either encasing or supporting the permanent magnetic element, the member, the lancet, the mechanical or electrical force, the lever member, and the activator."

Applicant is unclear of the examiner's rejection with respect to Claims 27 and 28. The basic recitation in these claims is that one of the permanent magnetic element and the member is free to pass through the other, which means that the inner diameter of one is big enough to accommodate the outer diameter of the other so that it can pass through. See paragraph 19, as Kheiri's device has a magnet **50** that is capable of passing through bobbin **35**.

Applicant argues that it would not be obvious to combine the lever member of LeVaughn to the device of Kheiri. The examiner disagrees and maintains the position above in paragraph 21, in that mechanically separating the retracted and piercing positions to avoid unintentional piercing of the lancet is an important safety measure if

for some reason the electric current is applied accidentally, and would have been obvious to one of ordinary skill in the art.

Applicant argues that the electric current of Kheiri is not to be considered as the "arming element." However, applicant defines "arming" as a process going from a steady state (when lancet will not project out) to fully armed (when it is ready for being activated and projecting out), a process which the electric current controls in the device of Kheiri, and therefore reads on this limitation (see paragraph 19).

Lastly, applicant argues that a depth adjuster and cocking tube, as well as a dial adjuster and follower are not obvious over Kheiri, Simons et al., and LeVaughn since Kheiri has an end cap to control the depth of puncture. However, as maintained in paragraph 22 above, it would be obvious to implement additional depth adjustment mechanisms for fine tuning, as it is important for the patient to lower pain levels during puncture.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "MJ Hayes", with a stylized, cursive script.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER